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SECTION 6
BASELINE HUMAN HEALTH RISK ASSESSMENT

Notes to EPA reviewers:

1) Because this Risk Assessment is being written as a chapter in the RI, some information that would usually be included if the document were to be issued as a stand-alone report is not presented here. Rather, some information is given in other sections of the RI.

2) All calculations of exposure and risk are DRAFT and are subject to change based on on-going validation as well as changes in exposure parameters and exposure data

6.1 OVERVIEW

6.1.1 Purpose of This Section

This section is a baseline human health risk assessment for OU1 of the Libby Asbestos Superfund Site. The risk assessment evaluates the health risks to people who may breath asbestos in air while working in or visiting OU1, either now or in the future, based on the conditions that currently exist within OU1. The methods used to evaluate human health risks from asbestos are in basic accord with USEPA guidelines for evaluating risks at Superfund sites (USEPA 1989, 1991a, 1991b, 1992, 1997), although some methods are modified to account for special issues regarding the quantification of exposure and risk from asbestos.

It is important to emphasize that there are a number of data limitations and uncertainties that limit the accuracy of the risk evaluations presented here. The USEPA is presently pursuing multiple efforts to increase our understanding of how to evaluate human exposure and risk from asbestos in general, and from LA in particular. However, because OU1 is currently scheduled to be developed as a public park, a risk assessment is needed at the preset time, despite the current limitations in our knowledge. For this reason, the results presented here should be recognized as interim estimates and approximations rather than highly precise values, and it should be understood that values may change in the future as further information becomes available.

6.1.2 Background Information on Asbestos

Mineralogy of Asbestos

Asbestos is the generic name for the fibrous habit of a broad family of naturally occurring poly-silicate minerals. Based on crystal structure, asbestos minerals are usually divided into two groups: serpentine and amphibole.

- Serpentine: The only asbestos mineral in the serpentine group is chrysotile. Chrysotile is the most widely used form of asbestos, accounting for about 90% of the asbestos used in commercial products such as insulation, friction products, floor tiles, cement building materials, textiles, etc. (IARC 1977). There is no evidence that chrysotile occurs in the Libby vermiculite deposit, although it may be present in some types of building materials in Libby.

- Amphiboles: Five asbestos minerals in the amphibole group have found limited use in commercial products (IARC 1977), including:

  - asbestiform actinolite
  - asbestiform cummingtonite-gruenerite (amosite)
  - asbestiform anthophyllite
  - asbestiform rebeckite (crocidolite)
  - asbestiform tremolite

At the Libby site, the form of asbestos that is present in the vermiculite deposit is an amphibole asbestos that for many years was classified as tremolite/actinolite (e.g., McDonald et al 1986, Amandus and Wheeler 1987a). More recently, the U.S. Geological Service (USGS) performed electron probe micro-analysis and X-ray diffraction analysis of 30 samples obtained from asbestos veins at the mine (Meeker et al. 2003). Results indicate that a variety of amphibole types exist at this site, including winchite, richterite, tremolite, actinolite, and magnesioriebeckite. The EPA does not believe that it is important to attempt to distinguish between these various amphibole types, and simply refers to this mixture as Libby Amphibole (LA).

Particle Size Variability

Not all asbestos fibers are of the same size. Individual fibers may vary in length and in width. This is important because it is currently suspected that the cancer potency of asbestos may be influenced by the size of the fiber. In general, LA fibers tend to be about 0.1 to 1 um thick, and can occur in a range of lengths from less than 1 um to over 100 um.

Measurement Techniques for Air

In the past, the most common technique for measuring asbestos in air was phase contrast microscopy (PCM). In this technique, air is drawn through a filter and airborne particles become deposited on the face of the filter. All structures that have a length of 5 um or more and have an aspect ratio (the ratio of length to width) of 3:1 or more are counted as PCM fibers. The limit of resolution of PCM is about 0.25 um, so particles thinner than this are generally not observable. A key limitation of PCM is that particle discrimination is based only on size and shape. Because

of this, it is not possible to classify asbestos particles by mineral type, or even to distinguish between asbestos and non-asbestos particles.

For this reason, nearly all samples of air collected in Libby are analyzed by transmission electron microscopy (TEM). This method operates at higher magnification (typically about 15,000x) and hence is able to detect structures much smaller than can been seen by PCM. In addition, most TEM instruments are fitted with one or both of two supplemental accessories that allow a more detailed characterization of a particle than is possible under light microscopy:

> EDS (Energy dispersive spectroscopy) provides data on the elemental composition of each particle being examined. This makes it possible to distinguish organic particles from mineral particles, and also allows for distinguishing between different types of minerals.
>
> SAED (selected area electron diffraction) provides the x-ray diffraction pattern for each particle. This information is helpful in distinguishing organic from mineral particles, and in classifying the type of asbestos (e.g. chrysotile vs. amphibole).

In some cases, it may be desirable to utilize results from a TEM analysis to estimate what would have been detected had the sample been analyzed by PCM. For convenience, particles detected under TEM that meet the rules for PCM are referred to as PCM-equivalent (PCME).

Measurement Techniques for Soil

Methods for the measurement of low levels (<1%) of asbestos in soil are not well established. EPA Region 8 evaluated a number of techniques for potential use at the Libby site (reference to PE study), and concluded that the most reliable method was polarized light microscopy using the visual area estimation technique (PLM-VE). This technique is facilitated by the use of site-specific reference materials that allow the microscopist to stratify a sample into one of the following semi-quantitative bins:

- Bin A: Non-detect
- Bin B1: Detectable at a level that is below the 0.2% reference material
- Bin B2: Detectable at a level higher than the 0.2% reference material, but less than the 1% reference material
- Bin C: Detectable at a level higher than the 1% reference material

The detection limit for this method (defined as the concentration of LA that results in high frequency of detects) is not known precisely, but is probably in the range of 0.1% to 0.2%.

A second method for characterizing soil contamination at the Libby site is visual inspection for vermiculite. As noted above, vermiculite contains LA, so the occurrence of visible vermiculite is

an indication of contamination with mine waste and LA. This too is a semi-quantitative method, and results are reported in four bins: none, low, medium, and high. The amount of vermiculite that may be present for each bin is variable, but the assignments are facilitated by the use of site-specific reference materials developed to guide the field crews (reference vis SOP).

6.1.3 Basis for Concern

Historic mining, milling, and processing of vermiculite at the Libby Superfund site are known to have caused releases of vermiculite and LA to the environment, including OU1. Inhalation of LA associated with the vermiculite is known to have caused a range of adverse health effects in exposed humans, including workers at the mine and processing facilities (Amandus and Wheeler 1987b, McDonald et al. 1986, McDonald et al. 2004, Sullivan 2007, Rohs et al. 2007), as well as residents of Libby (Peipens et al. 2003). Based on these adverse effects, EPA listed the Libby Asbestos Site on the National Priorities List in October 2002.

6.2 EXPOSURE ASSESSMENT

6.2.1 Conceptual Site Model

Figure 6-1 presents the Conceptual Site Model for how humans may be exposed to LA in OU1. Key elements of the model are described below.

Contaminated Media

The principal reason for concern at OU1 is that, when the site was occupied by the Export Plant, substantial quantities of vermiculite and LA were stockpiled and staged on the site in order to support shipment of vermiculite to other locations around the country. As a consequence of the operations at the site, substantial quantities of vermiculite were lost or spilled and became mixed into the soil of OU1. Because the vermiculite contains LA, this also contaminated the soil with LA fibers.

Although EPA has undertaken extensive cleanup activities at the site, including demolition of the former export plant and other contaminated structures as well as excavation and replacement of surface material at a number of locations across the site, the surface soil remains contaminated with visible vermiculite in a number of locations (see Figure 2-5). In addition, based on field observations and anecdotal information, it is suspected that substantial levels of vermiculite may remain at depth in some areas, which could serve as a source of release in the future if excavation activities brought contaminated material to the surface.

Land Use

As discussed in Section 1.2, in the past the site was used by W.R Grace for stockpiling and distributing vermiculite concentrate to other locations around the country. Portions of the site were also used for other commercial operations and for recreational activities.

Currently the site is owned by the City of Libby and is mainly undeveloped except for the David Thompson Search and Rescue facility and for boat launch facilities along the river. The City is presently planning to develop a public park on the site.

Exposed Populations

Consideration of current and future land use at OU1 indicates that there are four categories of humans who are likely to be exposed at OU1 on a regular basis, including:

- Volunteers who staff the David Thompson Search and Rescue Facility
- Fishing guides who launch fishing boats from the boat launce facility in OU1
- Local residents who visit the site for recreational purposes, either now or in the future after OU1 has been converted by the City into a public park
- City workers who perform maintenance activities at OU1, either now or in the future

Exposures of other humans who visit the site on a less frequent basis (e.g., out of town visitors, fishermen who go on float trips originating at the site, etc.) would be lower than the exposures for the populations above.

Exposure Pathways

Humans who visit or work at OU1 may be exposed to LA either by incidental ingestion of contaminated soil or by inhalation of air that contains LA fibers. Of these two pathways, inhalation exposure is considered to be of greatest concern. To the extent that incidental ingestion exposure of soil may occur, the added risk from this pathway compared to the inhalation pathway is likely to be very small, so only the inhalation pathway is quantified in this assessment.

Because LA fibers are solid, they does not exist in air except as a consequence of some source material (e.g., contaminated outdoor soil or indoor dust) being disturbed by some sort of force. This may include natural forces such as wind blowing over a contaminated soil, or human activities such as sweeping up dust indoors or mowing/raking/digging in areas of contaminated outdoor soil. The amount of LA in air, and hence the amount inhaled, will vary depending on the level of LA in the source and also on the intensity of the activity that each person is engaged in. For the purposes of this assessment, inhalation exposures are separated into two categories, as follows:

- Active behaviors are human activities that are expected to disturb LA in a source material such as outdoor soil or indoor dust. For example, digging in the soil would rank as an active behavior, as would sweeping up indoor dust with a broom.

- Passive behaviors are human activities that are not likely to substantially disturb source materials such as soil or dust. For example, sitting on a blanket during a picnic at the park would rank as a passive behavior, as would most indoor activities that do not actively disturb dust.

Volunteers at the David Thompson Search and Rescue Facility may be exposed both while inside the facility, and while working outside in the vicinity of the building. At both locations, exposures may consist of a mixture of active and passive behaviors. Data were not collected on the ratio of time outdoors that ranks as active and passive, so a default ratio of 25:75 passive was assumed for both CTE and RME receptors.

Fishing guides who launch boats fro the boat launch ramp are expected to be exposed only outdoors. Because the boat ramp is paved, exposures from soil disturbance may tend to be low, but could occur as a result of disturbing dust from OU1 that has fallen onto the ramp. Likewise, fishing guides might be exposed by disturbing soil when parking their vehicles in non-paved areas. Data were not collected on the ratio of time outdoors that ranks as active and passive, so a default value of 33:67 (active:passive) was assumed for CTE receptors, and 50:50 for RME receptors.

Current or future recreational visitors to the site (park visitors) are also assumed to be exposed only outdoors. It is assumed that park visitors might engage in a wide variety of different types of behaviors, ranging from passive (e.g., sitting at a picnic table) to active (e.g., playing sports, a child digging in the soil, etc.). A default value of 20:80 (active:passive) was assumed for both CTE and RME receptors.

City maintenance workers are assumed to engage in a variety of activities at OU1, the most common of which would be lawn care and repair or maintenance or facilities. This might include occasional work inside the David Thomson building or in the pump house, but because such indoor exposures are likely to be a minor source of exposure compared to exposure that occur outdoors while maintaining the park, these potential indoor exposures are not evaluated quantitatively. A default value of 33:67 (active:passive) was assumed for CTE receptors 60:40 for RME receptors.

Note that all individuals who visit the site by car might be exposed by transfer of contaminated soil from the site into the car, followed by subsequent inhalation exposure while driving. No data are presently available to evaluate the potential significance of this pathway.

6.2.2 Basic Exposure Equation

Risk of disease from exposure to asbestos in air is related to the amount of asbestos inhaled. This, in turn, is related to the concentration in air, and the amount of time that inhalation exposure occurs. The basic equation is as follows:

$$C_{TWA} = C \cdot ET/24 \cdot EF/365$$

where:

C_{TWA} = Time weighted average concentration (f/cc)
C = Actual inhaled concentration (f/cc)
ET = Exposure time (hours per day that exposure occurs)
EF = Exposure frequency (day/year that exposure occurs)

For example, if a person were exposed to 0.1 f/cc for 8 hrs/day for 100 days per year, the value of C_{TWA} for that year would be computed as follows:

$$C_{TWA} = 0.1 \text{ f/cc} \cdot 8/24 \cdot 100 / 365 = 0.0091 \text{ f/cc}$$

6.2.3 Human Activity Parameters

Data on ET (hrs/day) and EF (days/year) were obtained by questionnaire for individuals who are currently exposed at OU1, including 18 volunteers at the Search and Rescue facility, 8 fishing guides, and one City maintenance worker. The detailed results of the survey are provided in Appendix A, and summary statistics for rescue volunteers (N = 18) and fishing guides (N = 8) are presented in Table 6-1. Because a response was obtained for only one City maintenance worker, and because the duties and exposure parameters of a maintenance worker are likely to change after the site is converted into a public park, exposure parameters for this worker were based on professional judgment, as were parameters for future visitors to the city park. These judgment-based parameters are shown in Table 6-2.

6.2.4 Concentration Values in Air

Concentration values of LA in air were derived from TEM measurements made at the Libby site. Data are expressed in terms of total LA structures per cubic centimeter of air (s/cc). This includes all amphibole structures with appropriate morphology that have an SAED pattern and an EDXA spectrum that are consistent with LA, that have a length greater than or equal to 0.5 um, and have an aspect ratio greater than or equal to 3:1.

Ambient Air

As discussed in Section 4.3.1, the average concentration of LA in ambient air in OU1 was estimated by averaging the concentration values measured at four near-by ambient air monitoring stations that collected samples once per 10 days from October 2006 to September 2007. Each of these samples was a 5-day sample. Summary statistics are presented in Table 6-3.

Indoor Air

The only building that presently exists at OU1 that is regularly occupied by humans is the Search and Rescue building. As discussed in Section 2.1.11.3 and Section 4.1, indoor air personal air samples were collected at this building to evaluate three exposure scenarios:

- Active behaviors in the garage area
- Active behaviors in the meeting room area
- Passive behaviors in the meeting room area.

Table 6-4 summarizes the results, stratified by location and by activity level.

As noted above, city maintenance workers might occasionally be exposed while working inside the pump house, but this is assumed to be a minor source of exposure for these individuals, so indoor exposure at this location is not evaluated quantitatively.

Outdoor Air Near Disturbed Soils

Only one data set is available on the concentration of LA in air near disturbed soils in OU1 under current site conditions. As discussed in Section 2.1.11.4 and Section 4.3.2, this data set consists of 8 personal air samples collected by an individual who was mowing ("brush hogging") in Area 1 to prepare for an inspection of soil for visible vermiculite contamination. The ABS data from this event are summarized in Table 6-5. These data provide one estimate of the level of exposure that may be experienced during soil disturbance activities at OU1, but the data may not be entirely representative, for the following reasons:

- Most of the ground was wetted before mowing to suppress dust releases
- The area mowed was a relatively small fraction of OU1, and levels of visible vermiculite in the area mowed are not as high as at some other locations in OU1
- The number of samples collected (N = 8) may not be large enough to capture the full range of variability in airborne releases during mowing or other soil disturbance activities, potentially leading to an underestimate of the mean air concentration that a worker might be exposed to.

Because of these potential limitations in the OU1-specific data set for air near soil disturbances, a second set of ABS data collected in Libby will also be used. This data set consists of 221 outdoor air ABS measurements collected as about 80 different locations during soil disturbance activities that included raking, mowing and digging.

At each location where ABS sampling occurred, the level of soil contamination was characterized in two ways:

- A 30 point composite sample was collected and analyzed by PLM-VE
- Each of the 30 points was inspected for visible vermiculite and assigned a value of none (no vermiculite visible), low (a few flakes of vermiculite), medium (more than a few flakes, up to a maximum of about 50% vermiculite), or high (nearly pure vermiculite).

For the purposes of this evaluation, the visible vermiculite data are selected as the preferred indicator of the level of soil contamination. This is because very few samples (3 out of 222) were positive for LA by PLM-VE and negative by visual inspection, but a number of samples (63 out of 222) were positive by visual inspection but negative by PLM-VE:

PLM-VE Result	Visible Vermiculite Result	
	Negative	Positive
Negative	102 (46%)	63 (28%)
Positive	3 (1%)	54 (24%)

This suggests that visual inspection is somewhat more sensitive in detecting soil contamination than PLM-VE.

The visual inspection data for each ABS area were converted to a visual score using the following equation:

$$VS = \frac{\sum N_i \cdot S_i}{\sum N_i}$$

where:

VS = Visible score
N_i = Number of observations of level "i"
S_i = Score assigned to an observation of level "i"

Based on information provided by field teams who perform visible inspections, the level of visible vermiculite in a location assigned a score of Medium is, on average, about 5-times higher than at a location assigned a score of Low, and a score of High is at least 2-times higher than a location scored as Medium. Based on this, the values selected for S_i are as follows:

Level	Score (S_i)
None	0
Low	1

Medium	5
High	10

The resulting data are summarized in Table 6-6. In an effort to quantify the relation, the data for each activity were fit to a Poisson lognormal model constructed as follows:

Count(observed) ~ Poisson(expected count)
Expected count = Volume examined · True Concentration
True Concentration ~ Lognormal(GM, GSD)
GM = a + b·Visible score
GSD = constant

Fitting was achieved using Bayes theorem utilizing Markov Chain Monte Carlo to evaluate the integral. [insert details from Brad Venner].

The resulting best fit lines are shown in Figure 6-2. The graphs on the left are plotted on a logarithmic scale. The pink lines plots the best fit of the geometric mean, and the blue line plots the best fit of the arithmetic mean. The graphs on the right are plotted on a linear scale, and show only the best fit of the arithmetic mean. The fitted parameters (slope and intercept) are listed below:

Activity	a (intercept)	b (slope)
Raking	0.0415	0.887
Mowing	0.194	4.15
Digging	0.785	16.77
Raking + digging	0.563	12.0
All combined	0.340	7.27

Inspection of these fitting results indicates the following:

- There are apparent differences between activities, with the highest releases being associated with the child digging scenario, and the lowest releases being associated with the raking scenario.
- The data are highly variable, both within and between activities. This high variability increases the difficulty in deriving reliable quantitative fits to the data.
- Because of the high variability, the arithmetic mean value for each activity is near the highest values that have been observed. That is, most observed values will be below the mean, but occasional high values are expected to occur, which substantially increase the mean. This is especially apparent in the child digging data set.

Based on these results, the concentration of LA in air for workers or site visitors during activities that disturb soil was estimated as follows:

Step 1: Identify the exposure location

For volunteers at the rescue facility, exposure locations were assigned based on responses to a questionnaire completed by each person. For fishing guides, exposure was assumed to occur mainly in Area A. For park visitors and maintenance workers, exposure was assumed to occur across all areas of OU1.

Step 2: Compute the Visible Score for each exposure area

The visible score for each exposure area was computed as described above, using the visual inspection data for OU1 summarized in Figure 2-5 and Figure 4-1. The results are shown in Table 6-7.

Step 3: Select the ABS data set(s) that are most nearly representative of the type of soil disturbance activity expected

For volunteers at the rescue facility, the nature of any outdoor soil disturbance activities was based on data provided in a questionnaire administered to all of the volunteers. In most cases, a combination of raking and digging was used. For fishing guides, the data for raking were used as a surrogate for simply walking or driving about the site, since it is not believed that fishing guides will either mow or dig at OU1. For recreational visitors at the park, the data for raking was selected to represent the CTE individual, while the average of raking and digging was selected to represent the RME individual. For a city maintenance worker, all of the three activities were combined, based on the expectation that the maintenance workers may routinely engage in raking, digging and mowing activities.

Step 4: Compute the Mean Concentration in ABS Air

Once the applicable ABS data set(s) were identified, the mean concentration in outdoor air near soil disturbances was computed from the equations fitted to the ABS data as follows:

$$\text{Average C(air) from soil disturbance} = a + b \cdot \text{Visible Score}$$

6.3 TOXICITY ASSESSMENT

The adverse effects of asbestos exposure in humans have been the subject of a large number of studies and publications. The following section is intended to provide a brief overview of the main types of adverse health effects that have been observed in humans. More detailed reviews of the literature are provided in IARC (1977), WHO (2000), and ATSDR (2001, 2004).

6.3.1 Non-Cancer Effects

Asbestosis

Asbestosis is a chronic pneumoconiosis associated with inhalation exposure to asbestos. It is characterized by the gradual formation of scar tissue in the lung parenchyma. Initially the scarring may be minor and localized within the basal areas, but as the disease develops, the lungs may develop extensive diffuse alveolar and interstitial fibrosis (American Thoracic Society 1986).

Build-up of scar tissue in the lung parenchyma results in a loss of normal elasticity in the lung which can lead to the progressive loss of lung function. The initial symptoms of asbestosis are shortness of breath, particularly during exertion. People with fully developed asbestosis tend to have increased difficulty breathing that is often accompanied by coughing or rales. In severe cases, impaired respiratory function can lead to death.

Asbestosis generally takes a long time to develop, with a latency period from 10 to 20 years. Mossman and Churg (1998) suggest that latency is inversely proportional to exposure level. The disease may continue to progress long after exposure has ceased (ATSDR 2001). The progression of the disease after cessation of exposure also appears to be related to the level and duration of exposure (American Thoracic Society 2004).

Pleural Abnormalities

Exposure to asbestos may induce several types of abnormality in the pleura (the membrane surrounding the lungs).

- *Pleural effusions* are areas where excess fluid accumulates in the pleural space. Most pleural effusions last only several months, although they may be recurrent

- *Pleural plaques* are acellular collagenous deposits, often with calcification. Pleural plaques are the most common manifestations of asbestos exposure (ATSDR 2001, American Thoracic Society 2004).

- *Diffuse pleural thickening* is a noncircumscribed fibrous thickening of the visceral pleura with areas of adherence to the parietal pleura. Diffuse thickening may be extensive and cover a whole lobe or even an entire lung. Infolding of thickened visceral pleura may result in collapse of the intervening lung parenchyma (rounded atelectasis). Gevenois et al. (1998) and Schwartz (1991) report that diffuse pleural thickening may occur as a result of pleural effusions.

Pleural effusions and plaques are generally asymptomatic, although rarely they may be associated with decreased ventilatory capacity, fever, and pain (e.g, Bourbeau et al. 1990). Diffuse pleural thickening can cause decreased ventilatory capacity (Baker et al. 1985, Churg 1986, Jarvholm and Larsson 1988). Severe effects are rare, although Miller et al. (1983) reported on severe cases of pleural thickening that lead to death.

The latency period for pleural abnormalities is usually about 10 to 40 years (American Thoracic Society 2004), although pleural effusions may occasionally develop as early as one year after first exposure (Epler and Gaensler 1982).

Other Non-Cancer Effects

Some epidemiological studies provide evidence that chronic exposure to asbestos can increase the risk of several other types of non-cancer effects including cor pulmonale (right-sided heart failure), retroperitoneal fibrosis (a fibrous mass in the back of the abdomen that blocks the flow of urine from the kidneys to the bladder), and depressed cell-mediated immunity (ATSDR 2001).

Observations of Asbestos-Related Non-Cancer Diseases in People Exposed to LA

Non-Malignant Respiratory Disease (NMRD)

Amandus and Wheeler (1987) and McDonald et al. (1986, 2004) studied the cause of death in workers exposed to LA while working at the vermiculite mine and mill at Libby. Sullivan (2007) also studied the cause of death in workers exposed to LA while working at the vermiculite mine and mill, as well as in workers employed at other facilities located in the town of Libby. Each of these researchers reported an increased incidence of non-malignant respiratory disease (NMRD) (i.e., asbestosis, chronic obstructive pulmonary disease (COPD), pneumonia, tuberculosis and emphysema) in exposed workers, supporting the conclusion that LA can cause increased risk of NMRD when inhaled.

Pleural Abnormalities

Armstrong et al. (1988), McDonald et al. (1986) and Amandus et al. (1987b) evaluated the prevalence of chest radiographic changes in workers exposed to LA while working at the vermiculite mine and mill at Libby. These researchers observed increased prevalence in pleural changes, including pleural calcification, pleural thickening and profusion of small opacities among exposed workers.

Rohs et al. (2007) studied the prevalence of pleural changes in the lungs of workers exposed to LA while working at a facility in Marysville, OH expanding Libby vermiculite for use as an inert carrier for lawn care products. Rohs et al. (2007) observed an increased incidence of pleural

plaques, diffuse pleural thickening and interstitial changes (irregular opacities) in exposed workers.

In addition, studies by Piepens et al. (2003), Muravov et al. (2005) and Whitehouse (2004) also observed increased incidence in pleural abnormalities of not only workers, but also household contacts of former employees of the Libby mine and residents of Libby, MT environmentally exposed to LA. These findings support the conclusion that exposure to LA can induce pleural abnormalities.

6.3.2 Cancer Effects

There are many epidemiological studies that have reported increased mortality from cancer in asbestos workers, especially from lung cancer and mesothelioma. Based on these findings, and supported by extensive carcinogenicity data from animal studies, EPA has classified asbestos as a known human carcinogen (USEPA 1993).

Lung Cancer

Exposure to asbestos is associated with increased risk of developing all major histological types of lung carcinoma (adenocarcinoma, squamous cell carcinoma, and oat-cell carcinoma) (ATSDR 2001). The latency period for lung cancer generally ranges from about 10 to 40 years (ATSDR 2001). Early stages are generally asymptomatic, but as the disease develops, patients may experience coughing, shortness of breath, fatigue, and chest pain. Most lung cancer cases result in death.

The risk of developing lung cancer from asbestos exposure is substantially higher in smokers than in non-smokers (Selikoff et al. 1968, Doll and Peto 1985, ATSDR 2001, NTP 2005). Although data are limited, it appears that the interaction between smoking and asbestos exposure is approximately multiplicative (Selikoff et al. 1968, Lee 2001, Henderson et al. 2004, ATSDR 2001, Hammond et al. 1979, Kamp et al. 1992, Mossman et al. 1996). That is, the effect of asbestos exposure is to multiply the risk that is attributable to all other sources of risk, with the size of the multiplier being related to the level and duration of asbestos exposure.

Mesothelioma

Mesothelioma is a tumor of the thin membrane that covers and protects the internal organs of the body including the lungs and chest cavity (pleura), and the abdominal cavity (peritoneal). The latency period for mesothelioma is typically around 20-40 years (Lanphear and Buncher 1992, ATSDR 2001, Mossman et al. 1996, Weill et al. 2004). By the time symptoms appear, the disease is most often rapidly fatal (British Thoracic Society 2004).

Other Cancers

Gastrointestinal cancer

NAS (2006) reviewed evidence regarding the role of asbestos in gastrointestinal cancers primarily following occupational exposures (these are assumed to be primarily by the inhalation route). NAS concluded that data are "suggestive but insufficient" to establish that asbestos exposure causes stomach or colorectal cancer. Data on esophageal cancer are mixed and were regarded as "inadequate to infer the presence or absence of a causal relationship to asbestos exposure".

Data on risks of gastrointestinal cancer following ingestion-only exposure are more limited. Some workers (e.g., Conforti et al. 1981, Kjaerheim et al. 2005) have reported a significant correlation between oral exposure to asbestos in drinking water and the risk of gastrointestinal cancer. However, WHO (1996) concluded that data are not adequate to support the hypothesis that an increased cancer risk is associated with the ingestion of asbestos in drinking water.

Laryngeal and Pharyngeal Cancer

NAS (2006) reviewed available data on the relationship between asbestos exposure and laryngeal cancer and concluded that the data were "sufficient to infer a causal relationship between asbestos and laryngeal cancer". NAS (2006) concluded that data are "suggestive but not sufficient to infer a causal relationship between asbestos exposure and pharyngeal cancer".

Renal Cancer

Excess deaths from kidney and bladder cancer among persons with known exposure to asbestos have been reported by a number of researchers (e.g., Selikoff et al. 1979, Enterline et al. 1987, Puntoni et al. 1979). A review by Smith et al. (1989) evaluated these studies and concluded that asbestos should be regarded as a probable cause of human kidney cancer.

Observations of Asbestos-Related Cancer Cases in Workers in Libby

Amandus and Wheeler (1987a, 1987b) and McDonald et al. (1986, 2004) studied the cause of death in workers exposed to LA while working at the vermiculite mine and mill at Libby. Both groups of researches reported an increased incidence of lung cancer and mesothelioma in exposed workers, strongly supporting the conclusion that LA can cause increased risk of respiratory cancer when inhaled. These studies are presented in greater detail in Appendix D.

6.3.3 Role of Fiber Type and Size in Adverse Health Effects

While all types of asbestos have been shown to induce asbestos-related disease in humans and in animals, there is considerable debate regarding the relative potencies of the various mineral types

and sizes. In particular, the carcinogenic potential of chrysotile asbestos relative to amphibole asbestos is a controversial issue. Based on lung burden studies, mechanistic studies, and some epidemiological data, some researchers (e.g., Hodgson and Darnton 2000, Mossman et al. 1990, McDonald and McDonald 1997) propose that amphibole fibers are more potent inducers of mesothelioma and potentially of lung cancer than chrysotile. This assertion has become known as the "amphibole hypothesis" which, in its strongest form, claims that pure chrysotile (i.e., without any associated amphibole fiber) would present little or no carcinogenic risk. However, the amphibole hypothesis is strongly disputed by other researchers. For example, Stayner et al. (1996) conducted a critical review of the supporting arguments suggesting that chrysotile asbestos has a lower carcinogenic potency than amphiboles. These authors found strong evidence from toxicological and epidemiological studies that occupational exposure to chrysotile asbestos is associated with an increased risk of both lung cancer and mesothelioma, and concluded that while chrysotile may be less potent than some amphiboles for inducing mesothelioma, the available evidence does not support a similar conclusion for lung cancer.

Studies of the importance of fiber size on toxicity come mainly from studies in animals, especially experiments conducted by Davis et al. (1978, 1980, 1985, 1986a, 1986b) and Davis and Jones (1988). These studies all utilized a common protocol in which groups of about 40 rats were exposed by inhalation for 7 hours per day, 5 days per week for 224 days over 1 year and then observed for at least another year. A range of different test materials were evaluated, including crocidolite, Korean tremolite, four types of chrysotile, and three types of amosite. Each type of asbestos was tested at an airborne concentration of 10 mg/m^3; several other concentrations were tested for some of the asbestos types. The original characterization of exposure materials in the studies by Davis et al. did not include comprehensive characterization of the distribution of the length and width of the suspended structures and did not include a count of structures thinner than 0.2 um. Because of these limitations, archived samples of the original stock samples were used to regenerate asbestos dust clouds (using the same equipment, procedures, and personnel as in the original studies) from which samples were taken and characterized more fully using TEM techniques (Berman et al., 1995).

Using these detailed particle size and type data, Berman et al. (1995) conducted statistical analyses of the rat lung tumor incidence data to identify which size categories were best correlated with increased incidence of disease. No mathematical model with a single explanatory variable provided an adequate description of the lung tumor incidence. In contrast, multivariate models which included concentrations of particles in different size categories provided an adequate description of the lung tumor incidence data. Fitting began with a model with 5 length categories (<5, 5-10, 10-20, 20-40, > 40 um) and five thickness categories (<0.15, 0.15-0.3, 0.3-1.0, 1.0-5.0, and > 5 um). By eliminating bins that had potency factors that were not statistically different from zero and combining bins that were not statistically different from each other, Berman et al. (1995) developed a final model with 3 length categories (<5, 5-40, and >40 um) and two width categories (<0.3 and > 5 um). The relative bin-specific potency factors for this model are summarized below:

Relative Potency Estimates Based on Rat Data

Width (um)	Length (um)		
	< 5	5-40	> 40
≤ 0.3	0	0.0017	0.853
≥ 5.0	0	0	0.145

Adapted from Berman (1995)

As seen, fibers longer than 40 um accounted for 99.8% of the total potency, with most of that (85%) being contributed by fibers ≤ 0.3 um in diameter. Only a small contribution (<0.2%) was provided by fibers 5-40 um in length, and fibers less than 5 um did not contribute any observable potency. Further analysis of the available data in the context of the best-fitting model could not discern a difference in the lung-cancer-inducing potency of chrysotile and amphibole. Statistical analysis of the mesothelioma data indicated that amphibole potency was greater than chrysotile potency for equivalent size and shape particles (Berman et al. 1995).

Studies on the importance of asbestos fiber dimension (length, width) on toxicity in humans are limited. Stayner et al. (2007) evaluated the role of fiber dimension on cancer and non-cancer disease in workers exposed to chrysotile. Both lung cancer and asbestos were most strongly associated with exposure to thin fibers (< 0.25 um). Exposure to long fibers (> 10 um) was found to be a strong predictor of increased lung cancer risk, while results for asbestos were inconsistent. No studies of this type have been located for workers exposed to amphibole. However, Berman and Crump (2003) performed mathematical modeling of human exposure-response data to a range of different asbestos types, and concluded that fibers < 10 um in length have very low carcinogenic potency compared to fibers longer than 10 um in length (see Section 6.4.2.3 for more details).

6.4 METHODS FOR QUANTIFICATION OF RISK

6.4.1 Non-Cancer Risk

At present, the USEPA has not established a method for characterizing the risk of non-cancer effects in people from inhalation exposures to asbestos. However, Region 8 has developed an interim method for characterizing non-cancer risks from inhalation exposure to LA based on data from a facility in Ohio that utilized vermiculite from the mine in Libby. The details of this approach are presented in Appendix B.

In brief, the risk of a non-cancer effect is described in terms of the Hazard Quotient (HQ), which is defined as the ratio of the cumulative exposure level (f/cc-yrs) attributable to he site divided by a exposure level (the Reference Concentration, or RfC) that is believed to be without significant risk of averse non-cancer effects:

$$HQ = CE / RfC$$

As detailed in Appendix B, the RfC for LA is:

RfC = 0.004 PCM f/cc-yrs

The site-related cumulative exposure to LA is calculated as:

$$CE = C_{TWA} \cdot ED$$

where:

CE = Cumulative exposure (f/cc-yrs), expressed in terms of PCME f/cc-yrs
C_{TWA} = Time weighted average concentration (PCME f/cc)
ED = Exposure duration (years)

HQ values that do not exceed a value of 1 are expected to be pose a low risk of adverse non-cancer effects, and are judged to be acceptable. HQ values that exceed a value of 1 are considered to pose a risk of non-cancer effects that is of potential concern, with the level of concern increasing in proportion to the magnitude of the HQ value.

6.4.2 Cancer Risk

6.4.2.1 IRIS Approach

In 1986, the USEPA used available data from published epidemiological studies of workers exposed to airborne asbestos in the workplace to select risk models and derive quantitative potency factors for both lung cancer and mesothelioma (USEPA 1986). These potency factors were then used in a life table approach to compute unit risk values for a number of different exposure scenarios. The results of this effort form the basis for the method that is currently recommended by EPA for characterization of cancer risk from inhalation exposures to asbestos (USEPA 1993, IRIS 2008). The details of this effort are presented in Appendix C, and the following text presents a general overview of the approach..

Potency Factor for Lung Cancer

For lung cancer, USEPA (1986) reviewed the available exposure-response data from epidemiological studies and determined that the data were well characterized by a relative risk model of the following form:

$$RR = \alpha (1 + KL \cdot CE10)$$

where:

RR = Relative risk of lung cancer for a worker with a specified level of asbestos exposure. The value of RR measured in an epidemiological study is the ratio of the observed deaths in an exposure group divided by the expected number of deaths in that group: RR = Observed / Expected

α = "Baseline" relative risk of lung cancer in unexposed members of the cohort compared to the reference population.

KL = Lung cancer potency factor for asbestos particles $(f/cc\text{-}yrs)^{-1}$

CE10 = Cumulative exposure to asbestos, lagged by 10 years (f/cc-yrs). Exposure is expressed in terms of PCM f/cc.

EPA (1986) reviewed published epidemiological studies of lung cancer risk in workers exposed to asbestos in the workplace and identified those that provided quantitative data on relative risk as a function of cumulative exposure. The data from each of these studies were then fit to the linear relative risk model to derive a series of estimates of the lung cancer potency factor KL. The resulting values ranged widely from, 0.01E-02 to 6.7E-02 $(PCM\ f/cc\text{-}yrs)^{-1}$. After excluding KL values associated with mining and milling, a value of 1.0E-02 $(PCM\ f/cc\text{-}yr)^{-1}$ was selected as the best estimate of the KL for lung cancer.

Potency Factor for Mesothelioma

For mesothelioma, USEPA (1986) reviewed the available data and determined that the exposure-response relationship was characterized by an absolute risk model of the following form:

$$Im = C \cdot Q \cdot KM$$

where:

Im = Incidence of mesothelioma in the exposed group. The value of Im is equal to the observed number of mesothelioma deaths divided by the number of person-years of observation:

Im = Observed deaths / Person-years

C = Concentration of asbestos in air, expressed in terms of PCM s/cc

KM = Mesothelioma potency factor for asbestos particles $(PCM\ s/cc\text{-}yrs^3)^{-1}$

Q = Cumulative exposure value (yrs^3), which depends on the time since first exposure (T) and the duration of exposure (d) as follows:

For $T < 10$	$Q = 0$
For $10 < T < d + 10$	$Q = (T-10)^3$
For $T > d + 10$	$Q = (T-10)^3 - (T-10-d)^3$

USEPA (1986) reviewed published epidemiological studies of mesothelioma risk in workers exposed to asbestos in the workplace and identified those that provided data on mesothelioma

incidence as a function of cumulative exposure. Quantitative exposure-response data that were adequate for fitting to the risk model were available for only four of the epidemiological studies. The fitted study-specific KM values for these 4 studies ranged from 1.0E-08 to 1.2E-07 (f/cc-yrs^3)$^{-1}$. Because there were only four studies available for direct fitting, other studies that reported data on the occurrence of mesothelioma cases but did not include sufficient exposure-response data to allow fitting the risk model, were utilized based on an assessment of the ratio of mesothelioma cases to lung cancer cases. Based on an evaluation of all the available studies, USEPA (1986) identified a best estimate value of 1E-08 (PCM f/cc-yrs^3)$^{-1}$ as the KM for mesothelioma.

Derivation of Unit Risk Values

Based on the potency factors derived above, USEPA (1986) used the life table approach to calculate the risk of death from lung cancer and mesothelioma for two different concentrations of asbestos for each of a series of different continuous (24 hr/day, 365 day/yr) exposure scenarios. By definition, the unit risk is the lifetime excess cancer risk divided by the exposure concentration. Resulting values are presented in Table 6-3 of USEPA (1986). Since that time, EPA (1993) has revised the approach for extrapolating risks from workers to people with continuous exposures, and the revised unit risk values are presented in Table 6-8.

If a unit risk is not available in Table 6-8 for the starting age and exposure duration values of interest, values may be estimated by non-linear extrapolation using the following equations:

$$UR_{a,d} = k1 \cdot [1-\exp(-k2 \cdot d)]$$

where:

$UR_{a,d}$ = Unit risk for a residential exposure beginning at age of onset "a" and extending for a duration of "d" years
k1 and k2 = empiric fitting parameters derived from the values in Table 6-8

Both k1 and k2 depend on age at onset. These relationships are well characterized equations of the following form:

$$k1 = b1 + b2 \cdot \exp(-a / b3)$$
$$k2 = b4 + b5 \cdot \exp(-a / b6)$$

where b1 to b6 are empiric fitting parameters. The resulting best-fit parameters derived by minimization of the sum of the squared errors are summarized below:

Parameter	Value
b1	-0.0176401
b2	0.2492567
b3	24.7806941
b4	0.0415839
b5	0.0039973
b6	-18.2212632

These equations may be used to estimate unit risks for any continuous exposure duration of interest for any age of onset between zero and 50. For example, the unit risk for a resident exposed from age zero to age 30 is computed as follows:

$k1 = -0.0176401 + 0.2492567 \cdot \exp(-0 / 24.7806941) = 0.232$
$k2 = 0.0415839 + 0.0039973 \cdot \exp(-0 / -18.2212632) = 0.0456$
$UR_{0,30} = 0.232 \cdot (1-\exp(-0.0456 \cdot 30)) = 0.17$

Note that three significant figures are carried during the calculation, but that the final result is expressed to only two significant figures.

The unit risk factor for the exposure scenario is then used to compute excess cancer risk (lung cancer plus mesothelioma combined) as follows:

$$\text{Cancer Risk} = C_{TWA} \cdot UR$$

Note that C_{TWA} must be expressed in units of PCM f/cc. The concentration of PCM f/cc is estimated from the concentration of total LA f/cc by multiplying by a constant referred to as the "risk-based fraction" (RBF):

$$C(PCM) = C(\text{Total LA}) \cdot RBF_{PCME}$$

The value of RBF_{PCME} is based on the observed fraction of all LA fibers that meet the counting rules for PCM fibers (length $\geq$ 5 um, aspect ratio $\geq$ 3:1, and thickness > 0.25 um). Based on data presently available (N = 25,682 LA fibers), the value of $RBF_{PCM} = 0.45$.

Potential Limitations to the IRIS Risk Method

Although the IRIS method is currently the only approach approved by EP{A for estimating cancer risks from inhalation of asbestos, there are a number of potential limitations.

The primary limitation of concern is that the potency factors derived by USEPA (1986) are based on measures of exposure expressed as PCM fibers. However, as noted earlier, the PCM method does not distinguish between different mineral classes of asbestos, and does not account for differing size distributions between different workplaces. Thus, cancer risk estimates based on

the 1986 potency factors may yield reliable estimates in some cases, but might either underestimate or overestimate risks in other cases, especially when the composition of the atmosphere is dissimilar to the atmospheres upon which the potency factors are based.

A second concern is that the unit risks derived by USEPA (1986) are based on mortality statistics from the 1970's. Thus, they may not be applicable to populations that are exposed to asbestos today. In particular, as life expectancy has increased, risks from asbestos exposure also tend to increase. Thus, predications based on the IRIS method may tend to be somewhat too low.

Because of these potential limitations, this risk assessment evaluates cancer risk using several alternative methods in addition to the IRIS method. None of these methods are currently approved for use by EPA, but the results do provide some information on the range of uncertainty in cancer risk predictions. These alternative methods are detailed in Appendix D, and are summarized briefly below.

6.4.2.2 Updated IRIS Approach

As noted above, the unit risk values derived by USEPA (1986) are computed using the life table approach based on national mortality statistics compiled for the year 1977. However, mortality rates tend to change over time, and life expectancy today is substantially longer than in 1977. To account for this, cancer risks are calculated using the same potency factors derived by USEPA (1986), but using national mortality statistics from the year 200 rather than 1977 in the life table calculations. This approach is referred to in this document as the "updated IRIS approach".

6.4.2.3 Berman-Crump Approach

Derivation of Bin-Specific Potency Factors

Berman and Crump (2003) noted the wide variability between the study-specific values of KL and KM derived in USEPA (1986), and hypothesized that this variability was attributable at least in part to differences in the composition (mineral type, particle size) of the asbestos to which workers were exposed in differing workplaces. They postulated that each observed study-specific potency value was a concentration-weighted average of the potencies of four differing asbestos types ("bins"), defined as follows:

Bins Used by Berman and Crump (2003)

Bin	Mineral Type	Thickness	Length
1	Amphibole	< 0.4 um	5-10 um
2			> 10 um
3	Chrysotile	< 0.4 um	5-10 um
4			> 10 um

The choice of these bins was based primarily on data from studies in rats which suggest that toxicity is best correlated with long fibers (> 40 um) with thickness less than 0.4 um, and that fibers shorter than 5 um have very little potency (Berman et al. 1995). However, because particle size data for workplace exposures do not generally include a bin with a length cutoff of 40 um, a length cutoff of 10 um was used instead.

In order to fit the 4-bin risk models to the available epidemiological data, it was necessary to specify exposures in each workplace in terms of each of the four bins rather than in terms of PCM fibers. This is a difficult challenge, because none of the epidemiological studies provided data on the relative amounts of asbestos in each bin. To solve this problem, the authors used TEM data from other studies to estimate the asbestos size distributions in each workplace along with information on the amounts of each type of asbestos (chrysotile, amphibole) to estimate the concentration of asbestos in each bin.

Given estimates of bin-specific concentrations at each workplace, the authors fit the 4-bin risk models to the available epidemiological data using the method of maximum likelihood (MLE), assuming a lognormal uncertainty distribution around each study-specific potency factor. The variability of each lognormal distribution was estimated based on a consideration of multiple sources of uncertainty in each study. The results of this effort are summarized below:

Point Estimate Values for Bin-Specific Potencies

Bin	Mineral Type	Length (um)	Width (um)	KL (lung cancer)	KM (mesothelioma)
1	Amphibole	5-10	< 0.4	0	0
2		> 10	< 0.4	2.34E-02	2.70E-7
3	Chrysotile	5-10	< 0.4	0	0
4		> 10	< 0.4	6.22E-03	3.51E-10

As seen, the best fit of the model to the data suggests that fibers shorter than 10 um have no significant potency for either lung cancer or mesothelioma. In addition, the results suggest that amphibole is more potent than chrysotile, especially for mesothelioma.

Risk Calculation

For the purposes of applying these results to the estimation of risk from LA in Libby, the potency factors for Bin 2 were combined with estimates of exposure expressed as LA fibers thinner than 0.4 um and longer than 10 um, and risks were computed using the life table approach based on mortality statistics from 2000. The concentration of fibers > 10 um and thinner than 0.4 um is estimated from the concentration of total LA f/cc by multiplying by the RBF for this size bin:

$$C(PCM) = C(\text{Total LA}) \cdot RBF_{L > 10,\, T < 0.4}$$

The value of $RBF_{L > 10, T < 0.4}$ is based on the observed fraction of all LA fibers that meet the size rules. Based on data presently available, the value of $RBF_{L > 10, T < 0.4} = 0.062$.

6.4.2.4 Derivation of Site-Specific Potency Factors

There are several epidemiological studies that have been performed at the Libby site, and data from these studies offers the opportunity to derive site-specific potency factors for LA.

Lung Cancer Potency Factor

There are three studies that provide exposure-response data on cancer risks in workers exposed to LA:

Amandus and Wheeler 1987b
McDonald et al. 1986
McDonald et al. 2004

These studies may be used to derived estimates of the lung cancer potency factor for LA by fitting the reported exposure-response data to the basic relative risk model for lung cancer:

$$RR = \text{Observed / Expected} = \alpha (1 + CE10_{PCM} \cdot KL)$$

The details are provided in Appendix D. In brief, potency estimates based on these studies range from about 0.02 to 1.3 $(\text{PCM f/cc-y})^{-1}$, depending on which data set is used and which fitting technique is employed. Based on a review of all of the pros and cons of each approach, a value of 0.36 $(\text{PCM f/cc-yr})^{-1}$ is selected as the most reliable value, since this is based on the best data set (longest follow-up, most appropriate measure of exposure), and utilized the most reliable fitting technique (the "exact" method).

Mesothelioma Potency Factor

In order to obtain an estimate of the LA-specific potency factor for mesothelioma, it is necessary to fit available epidemiological data on mesothelioma in workers exposed to LA to the basic risk model for mesothelioma:

$$Im = \text{Observed Cases / Person year of observation} = C \cdot Q \cdot KM$$

The studies by Amandus and Wheeler (1987b) and McDonald et al. (1986, 2004) provide some information on the occurrence of mesothelioma cases in workers exposed to LA, but none of the studies provide the data in a form that is adequate for deriving an LA-specific potency factor for mesothelioma.

McDonald et al. (2004) report 12 cases of mesothelioma, and tested three exposure-response models based on:

1. Average concentration in first 5 yrs of exposure
2. CE
3. Residence-weighted CE

None of these three models fit the data. This is perhaps not surprising because risk of mesothelioma increases as a cubic function of time since first exposure, and none of these metrices have that property.

In order to fit the data from a study to the standard risk model, the following data are needed:

- Number of cases
- Number of person years of observation
- The mean value of C_{PCM}
- The mean value of Q, which in turn requires the mean values for T (time since first exposure) and d (the duration of exposure)

The study by Amandus and Wheeler (1987b) provides values for all of these items except T. However, they state that the total number of person years was 13,502, and that there were 569 individuals in the cohort. This corresponds to an average of 23.7 PY per worker. Assuming that the cohort consisted of workers who were all exposed for 23.7 years, the value of KM based on this study is about 8E-09 (PCM f/cc-yrs^3)$^{-1}$ (see Appendix D for details). However, because of the high uncertainty in this value, the 95% upper confidence limit of the value is used instead. This value is 2.3E-08 (PCM f/cc-yrs^3)$^{-1}$.

Risk Calculation

For the purposes of applying these results to the estimation of risk from LA in Libby, the potency factors derived as described above were combined with estimates of exposure expressed as PCME fibers, and risks were computed using the life table approach based on mortality statistics from 2000.

6.4.2.5 Use of Multiple Methods to Characterize Uncertainty

As noted previously, the IRIS method is the only approach currently approved by EPA for evaluation of cancer risks from inhalation exposure to asbestos. However, because of the potential limitations associated with the IRIS method, this risk assessment includes risk estimated based on three alternative approaches, as described above:

- Updated IRIS
- Berman and Crump
- Site-Specific

Although none of these three methods have been approved by EPA, the results from these methods provides some information on the magnitude of the uncertainty associated with the cancer risk models.

6.5 RISK CHARACTERIZATION

6.5.1 Search and Rescue Workers

Cancer and non-cancer risks were calculated individually for each of the 18 members of the search and rescue squad that responded to the detailed questionnaire on their typical activity patterns while at OU1. Results stratified by individual and pathway are presented in Table 6-9, and the total risks are summarized in Table 6-10.

Non-Cancer Risks

Non-cancer risks, expressed in terms of the HQ for LA, exceed a level of concern for several of the workers, with values ranging from 2-3. The value for the CTE receptor is 1.2 and for the RME receptor (the 95th percentile) is 3.2.

Cancer Risks

Inspection of Tables 6-9 and 6-10 reveals the following main points:

- For most individuals, inhalation exposure to outdoor air during soil disturbance activities is the largest contributor to total cancer risk. However, exposure during indoor activities that disturb dust may contribute risk of a comparable magnitude in a few cases.
- Risks from inhalation of ambient air while outdoors at the facility is quite low. Risk from indoor air during passive activities is also low.
- Total cancer risks to individuals (summed across all exposure pathways that occur while at the facility) range from a minimum of about 2E-07 to a maximum of about 6E-05, depending on the individual and the risk calculation model. No value exceeds 1E-04.

6.5.2 Fishing Guides

Estimated levels of exposure and of cancer and non-cancer risk for current or future fishing guides who launch float trips from the boat ramp in OU1 are summarized in Table 6-11.

Non-Cancer Risks

As seen, non-cancer risks for fishing guides exceed a level of concern for the RME receptor (HQ = 4), but not for the CTE receptor (HQ = 0.9).

Cancer Risks

As seen, estimated risks for the CTE receptor range from 5E-06 to 1E-05, while risks to an RME receptor range from 2E-05 to 5E-05, depending on risk model. This risk is due almost entirely to inhalation of LA in air above disturbed soil or dust in Area A (the boat launch area).

6.5.3 Park Visitors

Estimated levels of exposure and of cancer and non-cancer risk for current or future park visitors are summarized in Table 6-12. Two different cases are considered. In the first case, exposure is assumed to occur at random across all of OU1 (i.e., the visitor does not always go to one part of the site). In the second case, it is assumed that the visitor does tend to always go to the same area of the site, and that the area is at the high end of the level of soil contamination (Area D).

Non-Cancer Risks

As seen, non-cancer risks do not appear to be of concern for a CTE park visitor, but are above a level of concern for RME park visitors, with values ranging from 40 to 60, depending on where exposure occurs.

Cancer Risks

As shown in Table 6-12, for random exposure across the entire site, estimated risks for the CTE receptor (individuals who do dot actively dig in site soil but only disturb soil by walking or running) range from 8E-06 to 2E-05, while risks to an RME receptor (an individual who is expected to dig in the soil while at the site) range from 1E-03 to 2E-03, depending on risk model. For preferential exposure in locations of high visible vermiculite, estimated risks for the CTE receptor range from 1E-05 to 3E-05, while risks to an RME receptor range from 1E-03 to 4E-03, depending on risk model.

As above, this risk is due almost entirely to inhalation of LA in air above disturbed soil.

6.5.4 Park Maintenance Workers

Estimated levels of exposure and of cancer and non-cancer risk for current or future park maintenance workers are summarized in Table 6-13. Park workers are expected to be exposed by all types of soil disturbance activities (mowing, raking and digging) al all locations across the site. Estimates of inhalation exposure are presented for two alternative data sources. In Panel A, ABS data are based on measurements in OU1 for the brush-hog scenario. For Panel B, ABS data are based on measurements from other locations that include mowing, digging and raking activities.

Non-Cancer Risks

As seen, non-cancer risks are above a level of concern for the RNME receptor when the brush hog data are used, and for both the CTE and RME receptor when the ABS data are used.

Cancer Risks

As shown in Panel A, if OU-1 brush hog data are used to evaluate exposure during soil disturbance activities, estimated cancer risks are in the range of 2E-06 to 4E-05. However, as noted previously, the OU-1 brush hog ABS data may not be entirely representative of air levels that might occur at the site. Risks estimates based on other ABS data (Panel B) suggest cancer risks may range from about 3E-04 to 5E-04 for a CTE worker and from 2E-03 to 5E-03 for an RME worker.

6.6 UNCERTAINTIES

As noted in the introduction to this Section, there are many uncertainties that limit confidence in the estimated risks of cancer and non-cancer effects in people who may visit or work at OU1. The principal sources of this uncertainty are discussed below.

6.6.1 Uncertainty in LA Levels in Soil

As discussed previously, characterization of LA levels in soil is difficult. At present, the best available technique is PLM-VE, but this method is semi-quantitative, and has a detection limit that is probably in the range of 0.1% to 0.2%. These levels of LA in soil are sufficiently high that disturbance can still result in the release of LA to air when the soil is disturbed. Thus, simply because a soil in non-detect by PLM-VE is not necessarily sufficient evidence that the soil in uncontaminated.

A second method for characterizing soil contamination at the site is the level of visible vermiculite. This method is also inherently subjective and semi-quantitative, so attempts to quantify the relationship between vermiculite levels in soil and the levels of LA in air when the soil is disturbed are especially difficult and uncertain.

6.6.2 Uncertainty in LA Concentrations in Inhaled Air

Concentrations of LA in ambient or personal air are inherently variable, so estimates of mean exposure concentrations are subject to uncertainty arising from random variation between individual samples. This problem is especially marked for outdoor ABS samples, where very wide variability (3-4 orders of magnitude) may be observed within and between data sets (see Figure 6-2). This high variability means that it is necessary to collect a large number of samples

to ensure that the data are representative. However, even when a large number of samples are available, estimates of the mean are still uncertain because of the wide variability.

This uncertainty is further compounded by the effect of analytical measurement error. That is, for each air sample collected, the measured concentration value is a random variable that is characterized by the Poisson distribution:

$$C_{observed} \sim \text{POISSON}(C_{true} \cdot \text{Volume analyzed}) / \text{Volume Analyzed}$$

As a consequence, the distribution of observed concentration values is characterized by a mixed distribution referred to as a Poisson lognormal (PLN). While statistical methods are available to estimate the parameters of a PLN data set, methods to characterize the uncertainty around the parameters are not well established. Because of this, it is not possible at present to reliably compute the 95% upper confidence limit of the mean of a PLN data set, and all of the calculations presented in this report utilize the best estimate of the mean. This approach could either underestimate or overestimate the true average level of exposure.

6.6.3 Uncertainty in the Non-Cancer Exposure Response Relationship

At present, EPA has not developed national guidance for evaluating the risk of non-cancer effects from inhalation exposure to asbestos. For this reason, Region 8 has developed a site-specific RfC based on data for workers exposed to LA in a facility in Ohio. This RfC is believed to be reasonable and appropriate, and to contain an adequate margin of safety. However, until this Regional value undergoes national peer review and validation, it must be recognized as an interim value that is subject to revision.

6.6.4 Uncertainty in the Cancer Exposure-Response Relationship

As discussed above, available data from animals and humans suggest that the risk of cancer from inhalation exposure to asbestos may depend in part on the type of asbestos (chrysotile vs. amphibole) and on the dimensions (length and width) of the inhaled fibers. At present, the method used by EPA for quantification of cancer risk from asbestos does not distinguish between fiber type, and considers only fibers that are longer than 5 um. EPA is presently working to refine the approach in order to account for differences in fiber type and size between different locations, but the method has not yet been reviewed or approved for use.

In this risk assessment, an effort was made to characterize the uncertainty in the IRIS risk model by computing risks using several alternative risk models as well as the IRIS model. In general, the differences in the predicted risks were relatively small (less than a factor of 5). These findings suggest that uncertainty in the most appropriate risk model to employ may not be as large a source of uncertainty as might have been anticipated.

6.6.5 Uncertainty in Human Exposure Patterns

Risk from asbestos is strongly dependent not only on the level of exposure, but also on the frequency of exposure and on the age when exposure begins and ends. Reliable data on the human exposure parameters are available for two of the populations evaluated (rescue volunteers and fishing guides), but data are not presently available for future visitors to the park or for maintenance works at the park. The exposure parameters selected for use in the calculation of risks for these populations were selected using professional judgment, with the intention of selecting values that are more likely to be high than low. However, true value are uncertain, and a survey of future park visitors and workers would be needed to derive more accurate and reliable values.

6.6.6 Uncertainty from Uncharacterized Waste Material

One of the uncertainties of potential concern at OU1 is the occurrence or residual vermiculite in subsurface soil. Although there are no quantitative data to characterize the volume that may be present below the soils that have currently been remediated, several lines of information suggest that the volume of buried vermiculite might be substantial. This includes the following:

- Former workers at the export plant report that large volumes of vermiculite were present in fill material used to level the site. It has been reported that between 20 to 30 feet of fill material was brought in to build up this site, and that some of this fill material originated from the mine.
- Cleanup activities completed to data at the site have identified substantial levels of buried vermiculite at some locations, including the north face of the site along the Kootenai River and along the berms to Highway 37 near the eastern end of the site. Vermiculite in these areas has been observed as layers; it is suspected these layers are the result of material that was stockpiled during the operation of the export plant being used to fill in low lying areas of the site.
- Installation of a water pipeline across the center of Area 1 by the City resulted in buried vermiculite being brought to the surface. During this excavation, vermiculite was observed a depths ranging from 10 to 36 inches below ground surface. Sample collected of the material indicated LA concentrations in the vermiculite were has high as 3%.
- Installation of a new phone line across the center Area 2 by a utility company also resulted in buried vermiculite being brought to the surface. During this excavation, vermiculite was observed at a depth of 24 inches below ground surface.

This information indicates that buried vermiculite at the site could serve as a potential source of release and re-contamination of surface soils under any circumstance in which subsurface soils might become exposed. This could result from natural weathering and erosion at the site, children or workers digging in the dirt, as well as a range of potential future construction activities that involve soil excavation or earthwork. Thus, regardless of the confidence in the

estimated risks to humans based on current site conditions, substantial concern exists for potential future risks that could result for exposure to vermiculites wastes that are presently buried.

6.7 SUMMARY

Although methods for quantification cancer and non-cancer risk from inhalation exposure to asbestos are still under development, risk predications based on the best methods and data that are currently available indicate the following:

- Non-cancer risks appear to be above a level of concern for all RME receptors and some CTE receptors
- Cancer risks appear to fall within EPA's risk range for current site users (rescue volunteers and fishing guides), but would likely be above EPA's risk range for future park visitors and workers.

This concern for protection of human health at OU1 is further supported by information that indicates substantial volumes of vermiculite may remain buried in subsurface soil at the site, because this material could be brought to the surface in the future by erosion of excavation. If so, risks under future conditions could be higher than under current conditions.

6.8 REFERENCES

NOT YET COMPLETE...needs to be updated

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